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09/864,510	05/24/2001	Gregory Murphy	28122.89	2445

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Eric B. Meyertons Esq.
MEYERTONS, HOOD, KIVLLIN, KOWERT & GOETZEL, P.C.
P.O. BOX 398
AUSTIN, TX 78767-0398

EXAMINER

LEWIS, RALPH A

ART UNIT PAPER NUMBER

3732

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary

Application No.

09/864,510

Applicant(s)

MURPHY ET AL.

Examiner

Ralph A. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 246-571 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 247, 250, 252, 263, 266, 268, 271, 274, 276, 279, 288, 290, 292, 295, 298, 300, 303, 305, 311, 314, 316, 318, 321, 327, 329, 334-336, 363, 370, 371, 401, 427, 428, 431, 444, 477, 506, 512, 513, 535, 541, 542, 564, 569 and 570 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/13/2004, 10/29/2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims allowed are 254-261,278,280-285,302,304,306-309,319,320,322-326,328,330-333,337-341,372-400,430,432-443,445-476 and 478-485.

Continuation of Disposition of Claims: Claims rejected are

246,248,249,251,253,262,264,265,267,269,270,272,273,275,277,286,287,289,291,293,294,296,297,299,301,310,312,313,315,317,342-362,364-369,402-426,429,486-505,507-511,514-534,536-540,543-563,565-568 and 571.

Withdrawal of Indicated Allowable Subject Matter

The previous indicated allowability of some of the allowed subject matter is withdrawn primarily in view of a closer reading of the V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52) reference.

Objection to Duplicate Claims

Claims 311, 305; 265, 249; 271, 279; 273, 287; 297, 312; 295, 303; 318, 327; 321, 335; 329, 336; 370, 401; 431, 444; and 477, 506 (at least) are objected to under 37 CFR 1.75 as being duplicates of one another. See MPEP § 706.03(k).

Objection to the Claims

Claims 246, 262, 270, 286, 294, 310, 318, 334, 342, 502 and 544 are objected to under 37 CFR 1.75(a) for failing to particularly point out and distinctly claim the subject matter which applicant regards as his/her invention

In claims 246, 262, 270, 286, 294, 310, 318, 334, 342 and 544 the claimed steps are confusingly out of order from that disclosed in the specification - see Figure 1.

Claim 502 confusingly repeats the limitations of claim 486 from which it depends.

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Rejections based on 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 422 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 422 confusingly appears to be comprised of several different conflicting claims.

Rejections based on Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 246, 248, 249, 251, 253, 262, 264, 265, 267, 269, 270, 272, 273, 275, 277, 286, 287, 289, 291, 293, 342-349, 352, 356, 358, 359, 364, 366-369, 402-409, 412, 416, 418, 423-426, 429, 486-493, 496, 500, 502, 508-511, 514, 544-551, 554, 558, 565, 567, 568 and 571 are rejected under 35 U.S.C. 102(b) as being anticipated by V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52).

V. Dor et al a method of reconstructing an enlarged left ventricle wherein an opening is made in the anterior wall of the left ventricle (LV) (page 48, column 1, line 2), a "limit" (or line) between the scarred heart tissue and normal heart muscle is established (page 48, column 1, lines 2 and 3), scarred tissue is removed (excluded, endocardectomy) (page 48, column 1, lines 9 and 10)(see also "resected" at page 48, column 2, line 14), an endoventricular circular suture is made at the limit (i.e. line" between the scarred tissue and the normal tissue (page 48, column 1, lines 24-26) a small rubber balloon is inserted into the left ventricle and inflated to the appropriate volume (page 48, column 2, lines 2-4), the left ventricle tissue is positioned around the balloon so that the new left ventricle volume can be checked (page 48, column 2, lines 2-3), the endocardial suture is tied to the inflated balloon (page 48, column 2, lines 5 and 6), the balloon is evacuated and removed (page 48, column 2, lines 6-7), and finally the opening is closed with an appropriately sized patch (page 48, column 2, lines 7-9).

In regard to the "shaper having a size and shape substantially equal to the size and shape of an appropriate left ventricle" limitation, the examiner notes that the V. Dor et al balloon is disclosed as being of the appropriate volume (i.e. size) and is illustrated

as being ellipsoid, it is not square or rectangularly shaped, it is not shaped as a star or disk, but rather it is shaped and sized for providing the surgeon with a tool for determining the proper size and an appropriate shape for the reconstructed left ventricle. It serves as a model for an appropriately shaped and sized left ventricle.

In regard to claim 251, it appears inherent from the V. Dor et al disclosure that the surgeon is viewing the operation and would at least in part use his/her vision for helping to make the determination.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 294, 296, 297, 299, 301, 310, 312, 313, 315 and 317 are rejected under 35 U.S.C. 103(a) as being unpatentable over V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52) in view of Hillegass et al (US 4,817,637), Kovacs (US 5,749,839) and Cook et al (US 5,964,806).

V. Dor et al fails to disclose what type of fluid is used to inflate the disclosed balloon. The prior art, however, is replete with teachings that silicone gel may conventionally be used for inflating medical balloon devices as is evidenced for example by Hillegass et al (column 3, lines 59-60), Kovacs (column 3, line 61) and Cook et al

(column 3, lines 49-53). To have selected silicone gel for the balloon inflation fluid as is well known in the art would have been obvious to the ordinarily skilled artisan

Claims 350-355, 410-415, 494-499, 523-528 and 552-557 are rejected under 35 U.S.C. 103(a) as being unpatentable over V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52) in view of Deslauriers et al (5,255,678).

V.Dor et al fail to disclose the actual shape of the disclosed balloon. Deslauriers et al, however, teaches that it is desirable to form left ventricle balloons in the shape of a left ventricle which may be either ellipsoidal shape as in Figure 9 or drop/pear/cone shaped as in Figure 10. To have shaped the V.Dor et al balloon so that it was the shape of the left ventricle as taught by Deslauriers et al would have been obvious to one of ordinary skill in the art.

Claims 357, 360-362, 365, 417, 419-421, 500, 501, 503-505, 507, 515-522, 529-534, 536-540, 543, 559-563, and 566 are rejected under 35 U.S.C. 103(a) as being unpatentable over V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52).

In regard to the limitations regarding the pressing of the ventricle against the shaper and the shaper having the firmness to resist deformation, it is noted that applicant provides for no explicit disclosure of such limitations, but as with applicant's disclosure, one of ordinary skill in the art would have found it obvious in V. Dor et al

procedure to pull and press on the ventricle tissue surrounding the balloon in order to ensure that the balloon is accurately filling the volume in the ventricle, otherwise, one would likely get inaccurate measurements in determining the volume. Moreover, it is noted that an inflated V. Dor et al balloon would have a given amount of firmness.

In regard to claims 365, 507, 515, 566, in any surgery it is common to hook the patient up to an ekg heart monitor, before, during and after the procedure in order to monitor the patient's condition. To have merely used a conventional ekg heart monitoring before, during or after the V. Dor et al procedure would have been obvious to one of ordinary skill in the art.

Allowable Subject Matter

Claims 247, 263, 271, 288, 295, 311, 370, 371, 427, 428, 512, 513, 541, 542, 569 and 570 are objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form to include all of the limitations from which they depend. Claims 254-261, 278, 280-285 and 302, 304, 306-309 are allowed. These claims include the limitation of "suturing a patch to an interior of the left ventricle." V Dor et al at page 48, column 2, lines 11-13 disclose the suturing of the patch on the "clothes line" but fail to indicate whether the patch is fixed inside the ventricle or not. The reference fails to provide any suggestion or motivation for attaching the patch internal to the ventricle.

Claims 250, 252, 266, 268, 274, 276, 290, 292, 298, 300, 314, 316, 363, 506 and 564 are objected to as being dependent on a rejected base claim, but would be

allowable if rewritten in independent form to include all of the limitations from which they depend. Claims 457-485 are allowed. These claims included the limitations of "beating heart . . . tactile feedback" and "detecting electrical pulses" V Dor et al at page 48, column 1, lines 3-6 disclose the determination of the limit or line between scarred and healthy tissue, but doesn't disclose how it is determined. It appears inherent from the disclosure that the surgeon is viewing the operation and would at least in part use his/her vision for helping to make the determination. There is no suggestion or apparent motivation provided in the reference for using tactile feedback or detecting electrical pulses.

Claims 318-333 are allowable over the prior art because it fails to teach or suggest expanding an expander positioned in the hollow of a shaper in the left ventricle as is set forth in the present claims. (note duplicate objection above with claims 318, 321, 327 and 329).

Claims 334-341, 372-401, 430-485 are allowable. Note duplicate claim objection above with respect to claims 335, 336, 431, 444 and 477.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (703) 872-9306. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Kevin Shaver, can be reached at (571) 272-4720.

R.Lewis
November 27, 2004



Ralph A. Lewis
Primary Examiner
AU3732